

EXHIBIT A

(Declaration Under 37 C.F.R. 1.131)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:)	Group Art Unit: 3733
)	
Stephen RITLAND)	Examiner: David C. COMSTOCK
)	
Application No. 10/624,234)	Confirmation No.: 7545
)	
Filed: July 21, 2003)	<u>DECLARATION UNDER</u>
)	<u>37 C.F.R. § 1.131</u>
Atty. File No.: 53693-11001)	
)	(FILED ELECTRONICALLY)
For: SURGICAL IMAGE TRACKER)	
MOUNTING BASE APPARATUS)	
AND METHOD OF USE)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

I, Stephen Ritland, being over the age of eighteen, declare as follows:

1. I am the sole inventor of U.S. Provisional Patent Application No. 60/397,191, entitled *Surgical Image Tracker Mounting Base Apparatus and Method of Use*, filed on July 18, 2002. A copy of the application and USPTO Filing Receipt are attached hereto as Attachment 1.

2. I am the sole inventor of U.S. Patent Application No. 10/624,234, entitled *Surgical Image Tracker Mounting Base Apparatus and Method of Use*, filed on July 21, 2003.

3. The invention entitled *Surgical Image Tracker Mounting Base Apparatus and Method of Use* was invented by me at least as early as July 18, 2002, the date of U.S. Provisional Patent Application No. 60/397,191.

4. The face of U.S. Patent Publication No. 2004/0172044 to Grimm et al. ("Grimm '044") shows Grimm '044 was filed March 8, 2004.

5. The face of U.S. Patent Publication No. 2004/0122305 to Grimm et al. ("Grimm '305") shows Grimm '305 was filed December 20, 2002.

6. The date of invention of the present application is at least July 18, 2002, the filing date of the U.S. Provisional Patent Application No. 60/397,191, and thus, my disclosure pre-dates the filing date of Grimm '305, that is, December 20, 2002.

7. I hereby declare that all statements made herein are of my own knowledge, are true, and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements are the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued therefrom.

Date: 8/9/9

By:

Stephen Ritland

ATTACHMENT A

(U.S. Provisional Patent Application No. 60/397,191 filed on July 18, 2002)



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
✓ 60/397,191	✓ 07/18/2002		✓ 80	✓ 4510-10-PROV	✓ 4		

22442
SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

RECEIVED

AUG 09 2002

SHERIDAN, ROSS

CONFIRMATION NO. 1242

FILING RECEIPT



OC00000008575897

Date Mailed: 08/06/2002

Receipt is acknowledged of this provisional Patent Application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

✓ Stephen Ritland, Flagstaff, AZ;

✓ If Required, Foreign Filing License Granted 08/05/2002

✓ Projected Publication Date: Not Applicable

✓ Non-Publication Request: No

✓ Early Publication Request: No

✓ **** SMALL ENTITY ****

Title

✓ Surgical image tracker mounting base apparatus and method of use

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

ok
cVR
9/27/02

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

Please type a plus sign (+) inside this box → ☐

PTO/SB/16 (8-00)

Approved for use through 10/31/2002. OMB0651-0032

U.S. patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the paperwork Reduction act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET
This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(s)/APPLICANT(s)		
Given Name (first and middle [if any])	Family Name or Surname	RESIDENCE (City and either State or Foreign Country)
Stephen	Ritland	1150 N. San Francisco Street Flagstaff, Arizona 86001

TITLE OF THE INVENTION (280 characters max)
"SURGICAL IMAGE TRACKER MOUNTING BASE APPARATUS AND METHOD OF USE"

CORRESPONDENCE ADDRESS					
Direct all correspondence to:					
<input checked="" type="checkbox"/> Customer Number	22442		→ Place Customer Number Bar Code Label here		
OR	Type Customer Number here				
<input checked="" type="checkbox"/> Firm or Individual Name	Sheridan Ross P.C.				
Address	1560 Broadway, Suite 1200				
City	Denver	State	Colorado	ZIP	80202-5141
Country	United States	Telephone	(303) 863-9700	Fax	(303) 863-0223

ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/>	Specification	Number of Pages	8	CD(s), Number	
<input checked="" type="checkbox"/>	Drawing(s)	Number of Sheets	4	X	Other (specify)
	Application Data Sheet. See 37 CFR 1.76				
	Postcard receipt				

METHOD OF PAYMENT FOR FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT	
<input checked="" type="checkbox"/>	Applicant claims small entity status. See 37 CFR 1.27
<input checked="" type="checkbox"/>	A check or money order is enclosed to cover the filing fees
<input checked="" type="checkbox"/>	The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number: 19-1970
	Payment by credit card. Form PTO-2038 is attached
FILING FEE AMOUNT (\$) \$80.00	

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.	
<input checked="" type="checkbox"/>	No.
<input type="checkbox"/>	Yes, The name of the U.S. Government agency and the Government Contract Number are:

Attorney Docket No.: 4510-10-PROV

Respectfully submitted,

Mark L. Yaskanin
Registration No. 45,246

Date: 7-18-02

EL923664691US

"EXPRESS MAIL" LABEL NUMBER: EL923664691US
DATE OF DEPOSIT: July 18, 2002

I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO ADDRESSEE" SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 20231.

TYPED OR PRINTED NAME: CONSTANCE ROBINETT

SIGNATURE: Constance Robinett

SURGICAL IMAGE TRACKER MOUNTING BASE APPARATUS AND METHOD OF USE

FIELD OF THE INVENTION

5 The present invention is a device and method of use for an apparatus used to mount
an image tracker to a patient during surgery.

BACKGROUND OF THE INVENTION

Due to the frequently limited amount of exposure of the spine or interior surgical
10 area, spinal implant procedures lend themselves to use of image guidance for surgery.
Examples of such image guidance systems include the BrainLAB System and the Stealth
System. The image guidance systems use data from standard CT or MRI scans to build a
three dimensional image of the patient's spine. This model is then electronically matched to
the patient's anatomy during surgery, allowing the surgeon, in effect, to see through tissue
15 in order to accurately determine the placement of instruments or devices. During the
operation, sensitive structures such as blood vessels and nerves, which the surgeon wants to
avoid on the way to the anatomical target, can be visualized. In addition, during the
operation the surgeon can follow the movements of his or her instruments on the computer
screen in real time.

20 As understood by those skilled in the art, these image guidance systems utilize a
computer system with a monitor and two cameras that emit infrared signals, thereby
determining the patient's position in the operating room as well as the position of the surgical
instruments in relation to the patient's spine. The infrared signals are continuously
monitored during surgery using an image tracker receiver that is located in the vicinity of the

surgical site. One method of tracking surgical instruments is to mount a surgical tracking receiver directly to a surgical instrument, such as a retractor. One alternative arrangement is to mount the image tracker to a mounting base that is temporarily inserted into a bone of the patient, near the surgical site.

5 Presently available mounting bases for inserting an image tracker temporarily into the bone of the patient tend to be unruly and cumbersome. One known base can easily become disengaged from its locked position, thereby requiring immediate attention to reestablish the proper tracking coordinates. The present invention provides is a mounting base for image tracker that addresses the difficulties associated with the currently available mounting
10 devices that are inserted into bone.

SUMMARY OF THE INVENTION

The present invention comprises a mounting base for an image tracker. The mounting base includes a stabilizing screw that is inserted through the base and then into the
15 bone. The mounting base interlocks with the stabilizing screw to hold the mounting base in a locked configuration. The image tracker is attached to the secured mounting base, thereby providing a secure mounting apparatus that can be used in the immediate vicinity of the patient's surgical site.

20

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of one embodiment of the present invention;

Fig. 2 is a second perspective view of the embodiment shown in Fig. 1;

Fig. 3 is a third perspective view of the embodiment shown in Fig. 1;

Fig. 4 is a fourth perspective view of the embodiment shown in Fig. 1.

DETAILED DESCRIPTION OF THE INVENTION

5 Referring to Figs. 1-4, one embodiment of the mounting base 10 comprising the present invention is shown. The mounting base 10 generally includes a body 12 having a first aperture 14 for receiving a securing mechanism 16. As best seen in Fig. 4, mounting base 10 further includes a second aperture 15 also for receiving securing mechanism 16. In a preferred embodiment, the first aperture 14 is situated along a side face 18 of the body 12 of base 10. Second aperture 15 penetrates a second surface of body 12, such as the bottom surface 19 of the base 10. Securing mechanism 16 may be any type of means for securing the base 10 to an object. Preferably, securing mechanism 16 is a bone screw having a plurality of threads 20 along the lower portion of its exterior. When a bone screw is used as securing mechanism 16, it serves to anchor the base 10 to a bone, such as the pelvis. The threads 20 of securing mechanism 16 allow securing mechanism 16 to be inserted into a bone target and rotated until a relatively tight insertion is reached.

Securing mechanism 16 includes a proximal end 22 having means for locking within the first aperture 14 of base 10. More particularly, the proximal end 22 of securing mechanism 16 includes a head portion 24. Locking means are provided between the head portion 24 of securing mechanism 16, and the interior surface 28 of first aperture 14. By way of example and not limitation, the locking means may preferably take the form of tongue and groove pairings, a ridge and valley coupling, texturing, protrusions that fit within slotted

openings, etc. More preferably, the locking means comprises partial concentric threads 26 on head portion 24 of securing mechanism 16, and discontinuous opposing projections and slots 27 within aperture 14. The partial concentric threads 26 interlock and mate with the discontinuous opposing projections and slots 27 positioned on the interior surface 28 of first aperture 14 when securing mechanism 26 is rotated such that partial concentric threads 26 line-up with the discontinuous opposing projections and slots 27 positioned on the interior surface 28 of first aperture 14.

In use, a surgeon decides upon a point for locating the base 10, and thus, the image tracker T. Image tracker T is typically located at a position situated near the surgical incision point on the patient, but spaced apart a sufficient distance such that the base 10 is not too close to the incision point so as to interfere with the surgeon's access and motion during surgery. The position for the image tracker base 10 is then properly prepared, which may typically include sterilization of the point of placement. A securing mechanism 16, such as a bone screw, is then threaded through both the first aperture 14 and second aperture 15 of the body 12. Subsequently, while the securing mechanism 16 is still threaded through body 12, the securing mechanism 16 is then inserted into the patient's bone. The securing mechanism 16 preferably includes a tool slot or receptacle along its top surface 36 for receiving a tool, such as a surgical screwdriver. The securing mechanism 16 is tightened into the bone so as to provide a relatively tight fit with the bone within which it is inserted. The body 12 is then interlocked with securing mechanism 16 by manipulating or turning the body 12 such that head portion 24 having a locking means, such as partial concentric threads 26, interlocks with the discontinuous opposing projections and slots 27 located on the interior

surface 28 of first aperture 14. Since head portion 24 preferably includes locking means along a limited circumferential area, it interlocks with the discontinuous opposing projections and slots 27 of interior surface 28 in first aperture 14 only when turned such that partial concentric threads 26 line up with the discontinuous opposing projections and slots 27 within
5 aperture 14.

In a separate aspect of the invention, a projection 30 located on the bottom surface 19 of base 10 may be used to provide added stability to base 10 during use. More specifically, projection 30 may take the form of a pin that serves to prevent rotational movement of base 10 while base 10 is anchored to an object, such as a bone. Projection 30
10 is preferably laterally offset from securing mechanism 16 and/or second aperture 15. Projection 30 may be of various length, and may be detachable and adjustable.

In a separate aspect of the invention, base 10 may also include an upper support structure 40 for receiving the image tracker T. Upper support structure 40 preferably includes a permanently mounted post 42 that may be used to detachably attach an image
15 tracker T using an interconnecting rod 44. In the preferred embodiment shown in Figs. 1-4, the interconnecting rod 44 is secured to post 42 using tightening screw 46.

In a separate aspect of the invention, first aperture 14 and second aperture 15 may be positioned along different surfaces of base 10. More particularly, first aperture 14 may be located along the top surface 32 of base 10, while second aperture 15 is located along a side
20 face 18, or bottom surface 19. Alternatively, first aperture 14 may be located along a side face 18, and second aperture 15 may also be located on a side face 18. Thus, with this last

alternative, when installed, securing mechanism 16 may not pass through either top surface 32 or bottom surface 19.

In a separate aspect of the invention, the alignment of first aperture 14 and second aperture 15 may be such that securing mechanism 16 is oriented at an angle θ relative to the side face 18 and bottom surface 19 of body 12. During manufacture of base 10, this orientation may be modified so that the angle θ varies. Various angles θ may be used to provide a series of bases 10 that have different orientations of the securing mechanism 16 relative to body 12, thereby allowing bases 10 to be used for different body locations and different body positions that may be desirable during a given surgical procedure.

All components of the invention described herein are manufactured of a material appropriate for surgical use. For example, the components can be made of stainless steel. However, it is to be understood that other types of materials may also be used, such as titanium or ceramics.

While various embodiments of the present invention have been described in detail, it is apparent that modifications and adaptations of those embodiments will occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention.

What is claimed is:

1. A device for stabilizing an image tracker in a patient's bone during surgery, comprising:

a securing mechanism;

a mounting base including a first aperture and a second aperture both sized to receive said securing mechanism, said first aperture including means for locking said mounting base to said securing mechanism;

wherein said securing mechanism is inserted through said first aperture and said second aperture of said mounting base and inserted into the patient's bone for temporarily stabilizing the image tracker to a patient.

2. The device claimed in claim 1, further comprising a stabilizing projection positioned on a bottom surface of said mounting base.

3. The device as claimed in claim 1, wherein said means for locking comprises a head portion including an interlocking pairing.

4. The device as claimed in claim 1, wherein said securing mechanism comprises a bone screw.

ABSTRACT

A device is presented for temporarily mounting an image tracker to a patient during surgery. The device preferably includes a first aperture and a axially-align second aperture. The apertures are sized to receive a securing mechanism, such as a bone screw. The bone screw preferably includes a head portion that interlocks with the interior surface of the first aperture, thereby temporarily interlocking the base to the securing mechanism, and thus, the patient.

M:\4510\10-PROV\Patent App.wpd

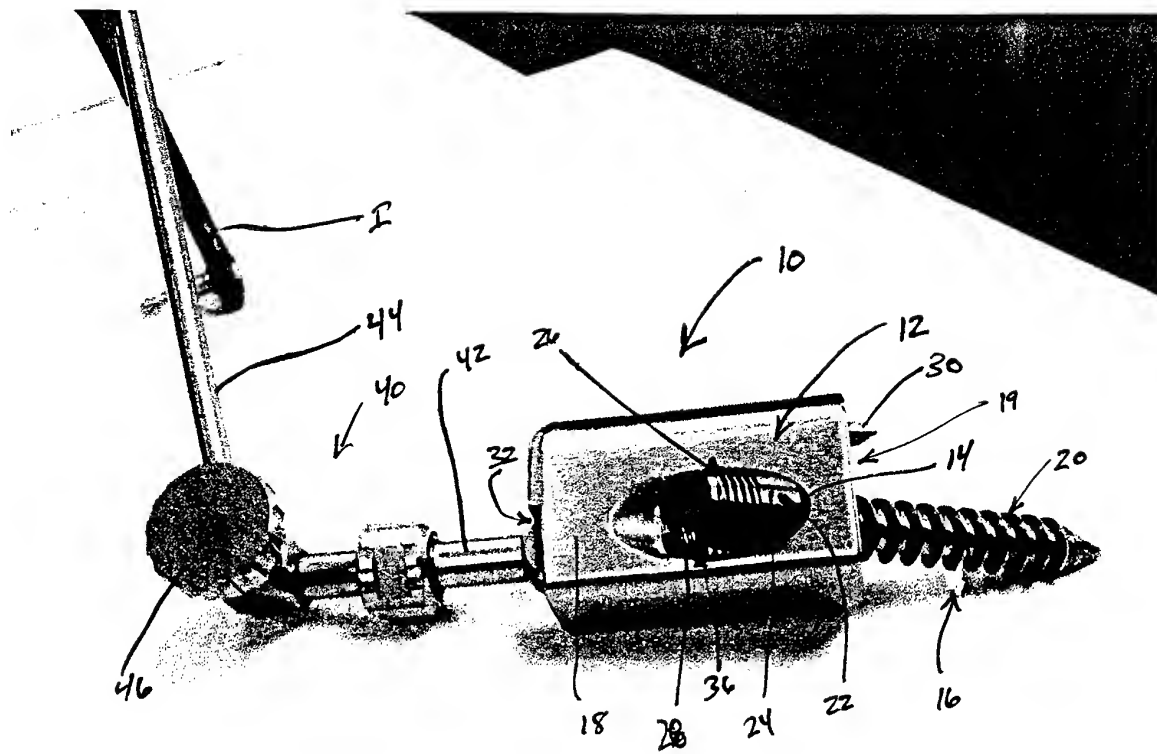


Fig. 1

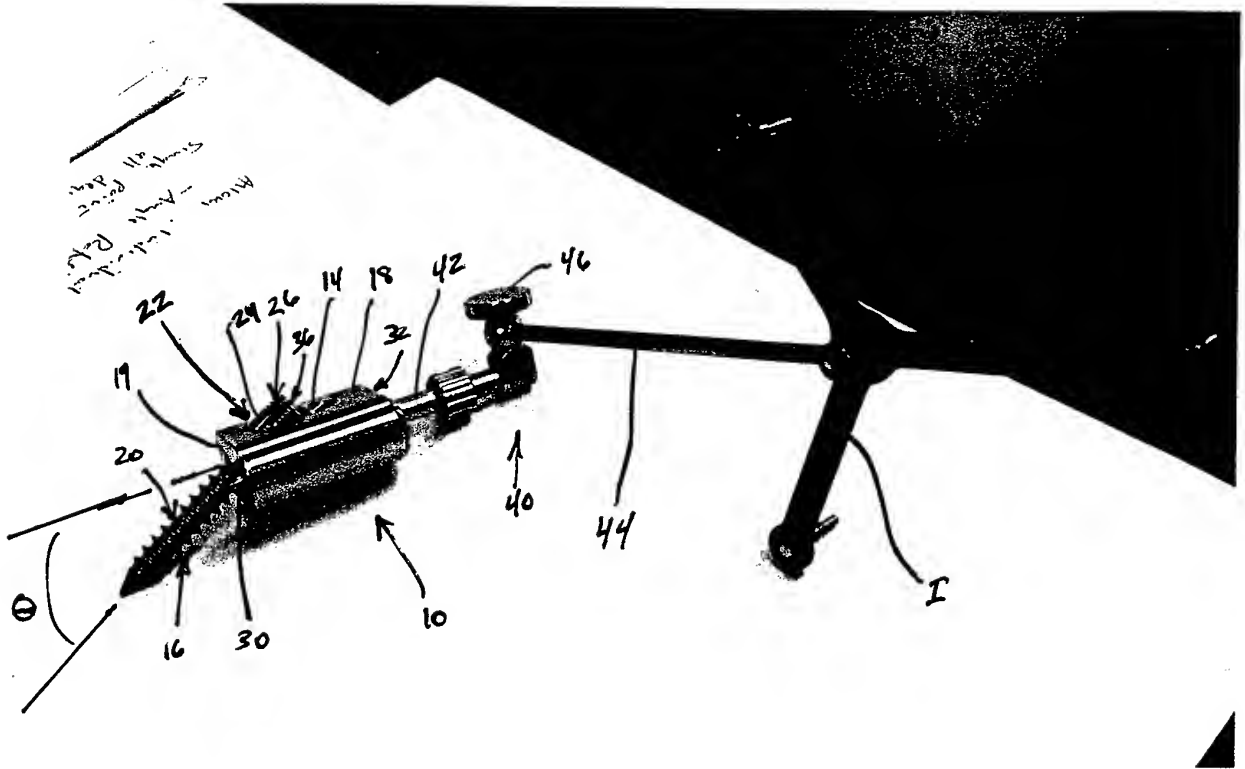


Fig. 2

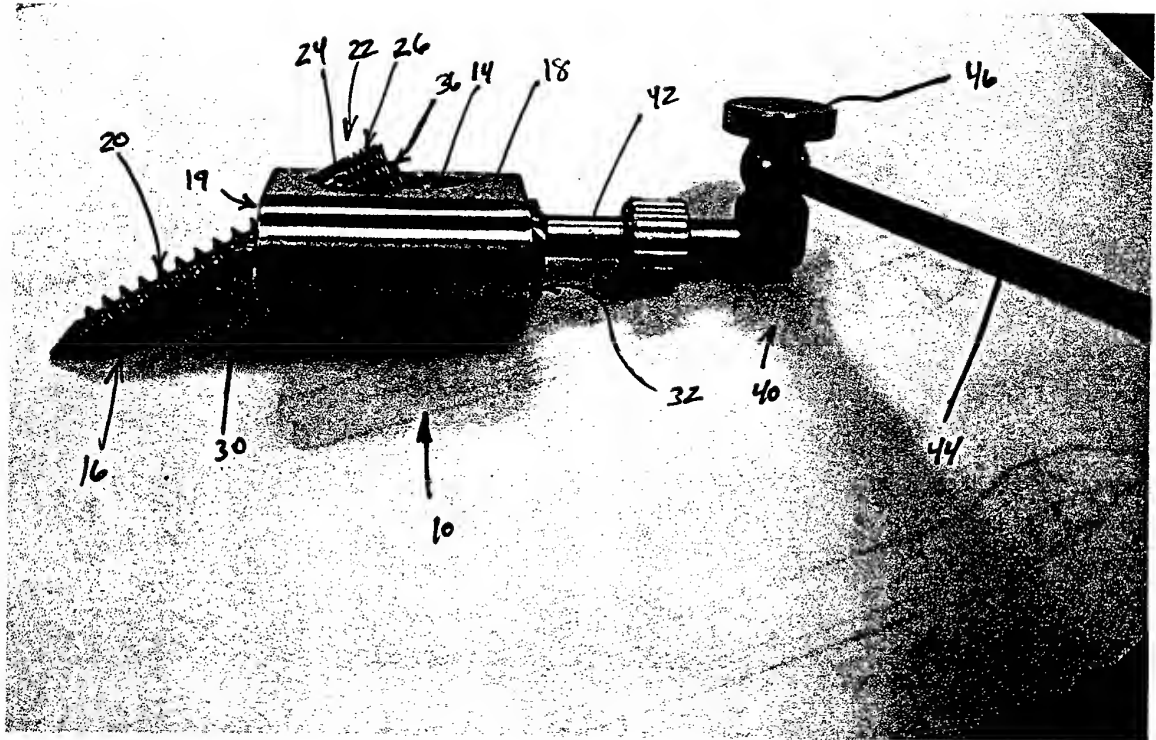


Fig. 3

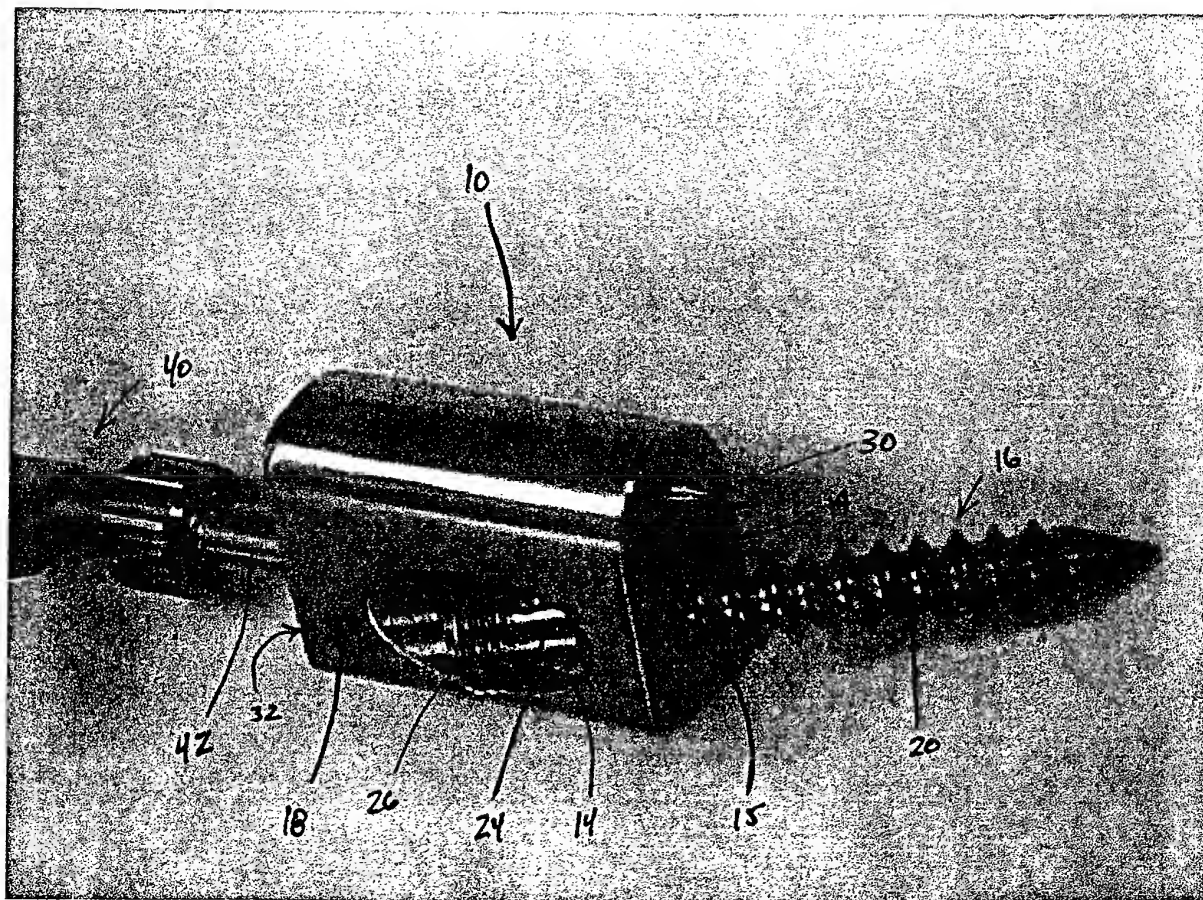


Fig. 4